DEPARTMENT OF HEALTH & HUMAN SERVICES

950980

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

November 17, 2004

VIA FEDEX

Re: MQSA Inspection ID # 2019880009

Eric Albert,
Radiology Manager
Community Hospital & Rehabilitation
Center of Los Gatos
815 Pollard Road
Los Gatos, CA 95032

Dear Eric Albert,

On July 7, 2004, a representative of the State of California, acting in behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA) which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following violations of the MQSA at your facility:

Level 2 (Repeat): Mammograms were processed in processor 0000000001, [redacted] Other, room: Darkroom at site Community Hospital & Rehabilitation Center of Los Gatos, when it was out of limits on at least 5 days. For example the mid-density was out of limits for a total of 5 separate days during the months of January – April of 2004 with no corrective action taken [21 CFR 900.12(e)(1)]

Level 2 (Repeat): Failure to produce documents verifying that the radiologic technologist [redacted] (11 CEU'S in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months. [21 CFR 900.12(a)(2)(iii) and 21 CFR 900.12(d)(2)]

Level 2 (Repeat): Failure to produce documents verifying that the radiologic technologist [redacted] (10 CEU'S in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months. [21 CFR 900.12(a)(2)(iii) and 21 CFR 900.12(d)(2)]

Level 2: Failure to specify adequate written procedures for collecting and resolving consumer complaints. [21 CFR 900.12(h)(1)]

These violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility. FDA may take additional actions, which may include, but are not limited to, the following:

- Requiring your facility to undergo an Additional Mammography Review;
- Placing your facility under a Directed Plan of Correction;
- Charging your facility for the cost of on-site monitoring;
- Seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards;
- Seeking to suspend or revoke your facility's FDA certificate; and
- Seeking a court injunction enjoining further mammography.

Please explain to this office in writing, within fifteen (15) working days after receiving this letter:

1. The specific steps you have taken to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;
2. The specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and
3. Sample records that demonstrate compliance for the non-compliances listed, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete corrective action within 15 working days, you should state the reason for the delay and provide a timeframe within which corrections will be completed. Please submit your response to this letter to:

Don A. Leeseberg, Jr., Radiological Health Specialist
United States Food & Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

There are many requirements applicable to mammography facilities. This letter pertains only to non-compliances related to the recent inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Don A. Leeseberg, Jr., Radiological Health Specialist at 510-337-6877.

Sincerely yours,

Barbara J. Cassens
District Director

cc:

Mr. Ed Gloor, MQSA Inspections Monitor
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